

G1.01.Requirement_proposal

Document: G1.01.Requirement_proposal

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Owner: Head of R&D Template Version: 5

1. Responsible

Jens Meder is the contact person for this requirement. The contact person accompanies this requirement over the entire life cycle.

2. Identifier

ARC-Req2_2: Analyse ecg data

3. Description

3.1. What should be improved/solved with the requirement?

- Analyze an ecg including all available ecg channels
 - Support for multiple ECG devices
 - Detect and annotate episodes of Atrial Fibrillation (AF) and Atrial Flutter (AFI) of 30s and more
 - Detect and annotate signal noise and artefacts in each channel
 - Calculate the atrial fibrillation burden (AF Burden) in terms of
 - · the longest episode of AF/AFI measured in seconds
 - the percentage of AF/AFI, e.g., 14% for a total of 42s of af in a 300s recording
 - Calculate the Heart Rate Variability (HRV) using root mean square of successive differences (RMSSD) in milliseconds
 - Calculate the signal quality in terms of net time without artefacts or signal noise
 - Calculate the heart rate (exclude noisy areas to avoid measurement errors)
 - Analysis result is uniquely identifiable (without referencing the specific patient)

3.2. Value

- Analysis result include following information:
 - AF was correctly detected and annotated
 - Noise was correctly detected and annotated
 - Calculated AF burden
 - Calculated HRV
 - Calculated signal quality
 - Calculated heart rate
- Authorized user can access the correct result
- Authorized user generally do not need more than 20 seconds to access the result
- The user needs maximum 3 seconds to classify the result.
- A printable document format is available.



- Notes for proposal:
 - The Analysis will have a medical purpose. This makes the following steps necessary:
 - More detailed acceptance criteria will be part of the validation plan and clinical evaluation
 - · Precise definition is therefore made in the corresponding process activities

3.3. Supported Devices

Bittium Faros

4. Exemplary use case

4.1. Use Case ARC-Req2_2-Uc1 (AF)

- Personas
 - Employee in a private medical practice
 - Desktop PC of the practice
- Preconditions
 - ECG data of a patient with AF is recorded and available for analysis
- Procedure
 - The ECG data is provided for analysis.
- Expected result
 - The employee interprets the visualized analysis result as AF.

1. Approval

Approver	Date and signature
РО	
Requirement Responsible	
R&D	